

Remarks

Claims 20-22, 28, 29, and 32-46 are pending in the subject application. By this Amendment, claims 20, 36, and 46 have been amended. New claims 47-49 are presented. No new matter has been introduced. Upon entry of these amendments, claims 20-22, 28, 29, and 32-49 will be before the Examiner. Favorable consideration of the pending claims is respectfully requested.

Claims 20-22, 28, 29, 32-43, and 46 stand rejected under §102(b) as anticipated by Cool *et al.* (European Publication No. 0470660A1). Applicants respectfully traverse. Cool *et al.* specify at column 1, lines 6-8, that the invention is a method for correcting the shape of a spinal column using a rod which consists of a material with a shape memory that has a "transition temperature which is lower than the body temperature...." All published claims of Cool *et al.* emphasize that characteristic. In stark contrast, all claims pending in the subject application contain the explicit limitation that the material generating the correction force has a transition temperature within the range of the patient's body temperature. This is nowhere taught by Cool *et al.*

It is a basic premise of patent law that, in order to anticipate, a single prior art reference must disclose within its four corners each and every element of the claimed invention. In *Lindemann v. American Hoist and Derrick Co.*, 221 USPQ 481 (Fed. Cir. 1984), the court stated:

Anticipation requires the presence in a single prior art reference, disclosure of each and every element of the claimed invention, arranged as in the claim. *Connell v. Sears Roebuck and Co.*, 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983); *SSIH Equip. S.A. v. USITC*, 718 F.2d 365, 216 USPQ 678 (Fed. Cir. 1983). In deciding the issue of anticipation, the [examiner] must identify the elements of the claims, determine their meaning in light of the specification and prosecution history, and identify corresponding elements disclosed in the allegedly anticipating reference. *SSIH, supra*; *Kalman [v. Kimberly-Clarke]*, 713 F.2d 760, 218 USPQ 781 (Fed. Cir. 1983)] (emphasis added). 221 USPQ at 485.

As Cool *et al.* fail to teach this element of the claimed invention, the transition temperature being within the range of the patient's body temperature, it cannot anticipate and therefore cannot support the §102(b) rejection. Reconsideration is respectfully requested.

Next, all pending claims are rejected under §102(e) as anticipated by Drewry *et al.* (U.S. Patent No. 6,783,527). Applicants respectfully traverse. This patent is primarily directed to anchors and coupling members for engaging a tensioning rod or other elongate corrective member, and is relatively quiet regarding the specific characteristics of the elongate member itself. In fact, Drewry is

completely silent about transition temperatures. A close reading of Drewry indicates that it relies on the elastic characteristics of the material used for elongate member **80** in generating the corrective force, not the superelastic characteristics of materials from which it might be made. This is evidenced at column 3, line 67 - column 4, line 2, which states "It is further contemplated that elongate member **80** has elasticity such that when tensioned it will tend to return toward its pretensioned state." (Emphasis added.) Even if Drewry's elongate member **80** is made from a superelastic material, and assuming for the sake of argument that the superelastic characteristics are relied upon for generating the corrective force (which is nowhere taught in the reference), Drewry says nothing about transition temperature of the material. It is not inherent that the transition temperature of the material will be within the range of the patient's body temperature as required by the pending claims. Evidence for this is provided by Cool *et al.*, which teaches a transition temperature lower than that of the patient's body temperature, and Sanders *et al.* (U.S. Patent No. 5,290,289, discussed in more detail below), which specifies a transition temperature above that of the patient's body temperature. Accordingly, it not being inherent that the Drewry materials have a transition temperature within the range of the patient's body temperature, and Drewry being otherwise silent about the transition temperature, Drewry fails to teach each and every limitation of the claims. Accordingly, Drewry cannot be used to support the §102(e) rejection of the pending claims. Reconsideration is respectfully requested.

Finally, all previously pending claims are rejected under §103(a) as obvious over Sanders *et al.* (U.S. Patent No. 5,290,289) in view of Cool *et al.* Applicants respectfully traverse. The Office Action asserts that Sanders discloses all of the claim limitations except for the corrective force being generated at body temperature, and suggests that Cool *et al.* would make it obvious to modify Sanders to provide for a rod designed to produce a correction force at body temperature instead of using external heating. This is an improper modification of the Sanders teachings and therefore fails to make a *prima facie* case of obviousness. As a matter of law one must take the full teachings of Sanders into consideration, and Sanders explicitly teaches away from using materials having a transition temperature at or below the patient's body temperature. For example, at column 4, lines 34-45, Sanders stresses the importance of being able to confine shape recovery forces to certain vertebral levels as desired by only applying heat to certain local areas of the correction rod, thereby minimizing the risk of neural damage or failure of the metal-bone interface:

Thus, post-operatively, additional correction may be attained by heating the rod to the shape transition temperature. Because of the segmental fixation, and the fact that the shape recovery of the alloy is a local phenomena, shape recovery forces may be confined to certain vertebral levels as desired by only applying the heat to certain local areas of the rod. Furthermore, the extent of heating, and, thus, the amount of shape recovery force, may be controlled so that the rod moves to its ideal shape to the degree that the spine can withstand without risking neural damage or failure of the metal-bone interface. Also, rotation of the spine due to scoliosis may be corrected by the torque exerted by the rod. (Emphasis added.)

This is again stressed at column 7, lines 38-57 of the '289 patent:

Post-operatively, the rod will apply corrective forces to the patient's spine if it is heated above the shape transition temperature and undergoes transformation to the parent phase crystal configuration. The shape-memory effect is a local phenomena. Thus, localized portions of the rod may be heated selectively in order to produce localized correctional forces applied only at selected vertebral levels. Moreover, by controlling the amount of heat transferred to the rod, the corrective forces may be produced gradually in whatever increments the physician deems appropriate. This minimizes the stress which must be borne by the fixation points and hence the probability of failure at the bone-metal interface. The incremental application of correctional forces also allows the physician to monitor the patient for any neural dysfunction as the treatment progresses as well as observe the spinal correction actually produced via fluoroscopy. The preferred method of heating is a radio frequency induction heater. (Emphasis added.)

Thus, to modify the teachings of Sanders by reducing the transition temperature to at or below the patient's body temperature such that no external heating means is necessary would destroy the intended benefits of the Sanders invention and is contrary to the explicit teachings of the reference. It is well established law that, "[i]f the proposed modification or combination of the prior art would change the principle of operation of the prior art invention, then the teachings of the references are not sufficient to render the claims *prima facie* obvious." MPEP § 2143.01, citing, *In re Ratti*, 270 F.2d 810 (C.C.P.A. 1959). Further, "if a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." MPEP § 2143.01, referencing, *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). Since modifying the teachings of Sanders by reducing the transition temperature to at or below the patient's body temperature would destroy the intended

benefits of the Sanders invention and is contrary to the explicit teachings of the reference, this rejection is improper and should be withdrawn.

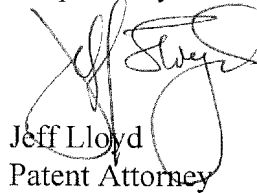
Applicants note that at page 5 of the Office Action, in response to Applicants' latest arguments of record, the Office Action mentions Siess *et al.* (U.S. Patent No. 7,027,875) for teaching Nitinol to be superelastic at body temperatures. This adds nothing to the previously cited references, as Siess *et al.* is completely silent about whether the transition temperature is at or below the patient's body temperature.

In view of the foregoing remarks and amendments to the claims, Applicants believe that the claims as currently pending are in condition for allowance, and such action is respectfully requested.

Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16 or 1.17 as required by this paper to Deposit Account 19-0065.

Respectfully submitted,



Jeff Lloyd
Patent Attorney

Registration No. 35,589

Phone No.: 352-375-8100

Fax No.: 352-372-5800

Address: Saliwanchik, Lloyd & Saliwanchik
A Professional Association
P.O. Box 142950
Gainesville, FL 32614-2950

JL/abt